Ethical Guidelines on Bio-Medical Research

1426. SHRI N. K. PREMACHANDRAN:
SHRI RAMACHANDRA KHUNTIA:

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether Government are aware of the recent trials on human subjects of an anti-cancer drug in Regional Cancer Centre at Thiruvananthapuram without following the rules properly;

(b) if so, whether any probe has been conducted into the incident;

(c) if so, the outcome of the same;

(d) whether Government propose to give interim relief to the victims; if not, the reasons therefor;

(e) whether Government propose to issue certain ethical guidelines on bio-medical research to avoid such incidents in future;

(f) if so, the details thereof; and

(g) the fresh steps taken to make rules relating to clearance for clinical trials more stringent?

THE MINISTER OF HEALTH AND FAMILY WELFARE (DR. C. P. THAKUR): (a) Yes, sir.

(b) to (d) A team constituted by the Central Government has investigated the alleged use of banned drug on cancer patients at Regional Cancer Centre, Thiruvananthapuram. The Central team observed that though violation of human rights or use of banned drug was not involved in the trial, however, there have been lapses in respect of the regulatory procedure required to be followed for conducting such trials in the country.

Regional Cancer Centre, Thiruvananthapuram has been served a show cause notice and advised to suspend all ongoing clinical trials with drugs for a period of six months. They have also been advised to obtain all necessary approvals from the government and revise the list of ethical committee members of the centre.

In view of above, the question of giving interim relief does not arise.

(e) and (f) Indian Council of Medical Research (ICMR), New Delhi has published "Ethical Guidelines for Bio-medical Research on human Subject" which will be followed by all researchers/institutions engaged in bio-medical research in the country.

(g) Government is amending the Drug and Cosmetics Rules to include provision for written permission from Drugs Controller General (India) for initiation of Clinical trials with new drugs on human.

Implementing statutory warning code in cigarette advertisements

1427. SHRI SUKHDEV SINGH LIBRA:
SARDAR GURCHARAN SINGH TOHRA:
SHRI RUMANDLA RAMACHANDRAIAH:

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether the Supreme Court has asked Government to take steps for implementing the statutory warning code in cigarette advertisements;

(b) if so, whether it has also sought Government's response on the ban on smoking in public places;

(c) whether the Court has said that the provisions of the Act were required to be implemented since they imposed sufficient restrictions to protect the health of citizens; and

(d) if so, the steps Government have taken in implementing orders of the Supreme Court?

THE MINISTER OF HEALTH AND FAMILY WELFARE (DR. C.P. THAKUR): (a) to (c) Yes, Sir. The Supreme Court has directed to take steps for strict compliance of statutory warning code in cigarette advertisements in accordance with the provisions of Cigarettes (Regulation of Production, Supply and Distribution) Act, 1975 and also passed orders prohibiting smoking in public places.

(d) A written communication has been sent from the Ministry of Health & Family Welfare to Chief Secretaries of all the States, Union Territories and Ministry of Finance requesting for taking necessary action for strict adherence of various provisions of the Cigarettes (Regulation of Production, Supply and Distribution) Act, 1975. As to the prohibition of smoking in public places, the Government has requested all the State Governments and Union Territories to give wide publicity to the orders of the Supreme Court. The Government has already introduced a comprehensive Bill in the Rajya Sabha on 7.3.2001 which, *inter-alia,* seeks to prohibit smoking in public places.